REMARKS

35 U.S.C. 102 Rejection

Claims 1, 3, 6, 8, 9, 10, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Rothgang.

Rothgang does teach the use of a dry urea, preferably in a compressed product although the powdered form can be placed in capsules, blister packs, etc. Once the specimen is deposited on the urea, water is added to the urea to initiate the reaction process. (Page 5, lines 17 – 18; lines 24 – 25 – page 6, lines 1 – 7) In accordance with the claims and the teachings within the Rothgang specification, the urea further comprises at least a buffer to set the pH value. (Page 5, lines 19 – 20) The indicator can either be mixed with the urea (Page 7, lines 10 – 11; page 9, lines 17-20), contained in the water used to activate the reaction (Page 7, lines 12-13) or on the test surface, such as filter paper (Page 7, line 13; page 9, lines 21-25 – page 10 lines 1-2)

In the instant invention as covered in Claims 1 - 17, there are two distinct, physically separated, compositions. The first is a finely powered urea and the second is the indicator, possibly combined with other materials such as agar, buffers, etc. In this embodiment of the instant invention, the only addition to the urea that is taught is the use of an anti-caking agent; a material that would be, at best, superfluous and at worst counterproductive, in the Rothgang teachings.

In the embodiments disclosed in Claims 1 – 17 of the instant invention, the specimen is first placed into the urea and then moved to the indicator, at which time the reaction starts, indicating either the presence or lack of presence of ammonia. There is neither the addition of water nor the exposure to both the urea and the indicator simultaneously taught in the embodiments of these claims.

In an alternate embodiment claimed in Claims 18 – 22 the urea and indicator have been combined, both in a powdered form. The combination in accordance with the instant invention does not, however, contain a buffer substance, as set forth in Rothgang Claim 1, (b). In Rothgang the thee ingredients are a) urea, b) buffer substance and c) pH indicator, with the reagent mixture containing at least the urea and buffer. The pH indicator, in accordance with Rothgang's claim 1, is not necessarily a part of the mixture.

Although the Rothgang patent teaches the weight of the compressed product, it does not address the particle size of any of the ingredients. As the embodiments of Rothgang call for the addition of water to dissolve the dry ingredients, particle size would be irrelevant.

Conversely, in the instant invention small particle size is advantageous. As stated on page 8, lines 8 – 11, the specimen is contacted with the composition, causing the urea to stick to the specimen. The specification specifically teaches at page 9 lines 10 – 19, that the smaller the particle size, the more efficient the test.

It is submitted that the differences between the Rothgang patent and the instant invention include, but are not limited to:

Marshall – pending claims	**Rothgang**
No water is added to the urea	Added water is required to activate the urea /buffer combination
No buffers are added to the urea	Buffers are required to be added to the urea in accordance with Claim 1
Dry indicators can be added to the urea	Indicators can be added to the urea or to the liquid used for activation
All ingredients are finely powered and loose within the respective testing area(s)	Urea/buffer combination can be compressed or put into capsules
Anti-caking material can be added to urea	Anti-caking would be unnecessary, or adverse, to the working of the invention
Finer urea particles increase efficiency	Particle size is not addressed

It is respectfully submitted that the currently pending amended claims reflect the differences between the instant invention and the Rothgang method for determining the presence of urease.

35 U.S.C. 103(a) Rejection

Claims 2, 4, 5, 7, 12, 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rothgang in view of King.

The King patent teaches a method to detect H. pylori by placing a specimen in a growth medium also containing urea and a pH indicator. Once the medium has been inoculated with the specimen, it is incubated for a period of time during which the pH indicator either changes color, indicating the presence of H. pylori, or remains the same, indicating the absence of H. pylori.

The Examiner states that the King patent teaches the user of an indicator in a gel form and that, when combined with the Rothgang, would produce the gel indicator of the instant invention. As stated heretofore, the Rothgang does not produce the instant invention and, the use of a gel indicator would not overcome the basic differences between the two methods.

The use of a gel indicator is disclosed in dependent claim 4 and included as part of the limitations of independent Claim 14. It is submitted that the applicant is not claiming a gel indicator in of itself, but rather the use of the indicator in combination with a unique method for testing. As a dependent claim, or a limitation within an independent claim, it is submitted that the **combination** of a gel indicator in a second area and powdered urea in a first area is patentable.

With respect to the use of agar to form gelatinous materials, this is well known in the medical arts and, in of itself, is not patentable. The use of agar in a unique combination, however, is patentable when used as a limitation for a patentable method.

With respect to the size of the urea, the King patent does not provide any specific sizes for

the urea. As the King patent is specifically directed to providing a growth medium which promotes the growth of H. pylori, the sizing of the urea is not of primary importance. It is stated in the instant specification at page 9, lines 8 – 19 that the finer the particles of urea, the more effective the test. It is respectively submitted King does not teach the use of fine particles of urea but rather concentrates the teachings to the growth medium.

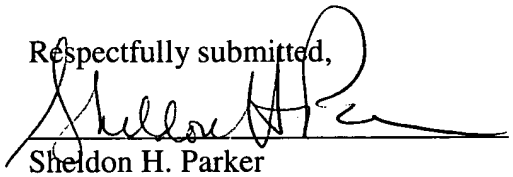
With respect to the use of phenol red, this is a common indicator and well known in the art. As with agar, applicant is not seeking patentability on this material. Applicant is, however, stating that the use of phenol red is patentable when used in combination with the novel method disclosed in the independent claims.

It is therefore submitted that claims 2, 3, 5, 7, 14 – 22 are patentable as all claims either include, or are dependent upon, a novel patentable method for determining the presence of urease.

CONCLUSION

In view of the above amendments and remarks, Applicant submits that the rejections and objections to the claims and specification have been overcome and the application is now in condition for allowance. Accordingly, Applicant respectfully requests that the rejections be withdrawn and the application be allowed.

Respectfully submitted,

Date: September 7, 2004 By: 

Sheldon H. Parker
Reg. No. 20,738

Jagtiani & Guttag
10363-A Democracy Lane
Fairfax, VA 22030
Telephone: 434-817-6606
Facsimile: 703-591-5907